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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,013	08/05/1999	DEBORAH KNUTZON	86014/8145	3773

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EXAMINER	
NASHED, NASHAAT T	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
11/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/367,013	KNUTZON ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/28/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *215-244,255-274 and 298-373* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *215-224,255-264,325,328,338,341,351,354,364 and 367* is/are allowed.

6)☐ Claim(s) *225-244,265-274,298-322,326,327,329-335,339,340,342-348,352,353,355-361,365,366 and 368-372* is/are rejected.

7)☒ Claim(s) *323,324,336,337,349,350,362,363 and 373* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/28/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Interview summary*.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2007 has been entered.

Claims 215-244, 255-274, 298-373 are pending and under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 235-244, 327, 340, 353, and 366 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the prior Office actions mailed 11/14/05 and 7/18/06.

Applicants continue to argue that the application meets the written description requirement and requested to reconsider the rejection in view of the court finding in Falkner v. Inglis, and submitted sequence alignments of SEQ ID NO: 2 with other 6-desaturases. They stated written description does not require any examples, and the written description can be met even where actual reduction to practice of an invention is absent.

Applicants arguments filed 8/28/07 have been fully considered, but they are found unpersuasive. Applicants are correct in that written description does not require example or structure of biological molecule as long as the written description is sufficient to allow one of ordinary skill in the art to recognize that applicants had possession of the claimed invention at the time the application was filed. Also, the view of the U. S. Court of Appeals, Federal Circuit are well known, and the Court have not provided any new insight with regard to the written description issues in Falkner v. Inglis. Claims to proteins and enzymes are allowed to a protein/enzyme from a particular organism having particular sufficient physical and chemical properties that would allow one of ordinary skill in the art to recognize the applicants had possession of the claimed invention. The amino acid sequence is just a property by which a protein/enzyme can be identified and described. The claims in the instant application are directed to methods and products using and comprising a broad genus of proteins,

which the specification and the prior art fail to support. The court of Appeals for the Federal Circuit has held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] name chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." UC California v. Eli Lilly (43 USPQ2d 1398). For claims drawn to genus, MPEP section 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Also, MPEP section 2163 states that a representative number of species mean that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The fact pattern in Falkner decision and the instant application are different because the state of the art is different. The claims in Falkner v. Inglis are directed to attenuated virus, whereas the claims of the instant application are directed to deletion mutants of the desaturase of SEQ ID NO:1. As indicated in the previous Office actions, the application fail to teach the various structural element of the protein, which may include the active site residues of the desaturase, the amino acid residues which are responsible for the substrate and regioselectivity of the enzyme. The specification provided no guidance to one of ordinary skill in the art, which amino acid residue(s) can be deleted without loss of enzymatic activity, regioselectivity of the reaction that it catalyzes, and substrate specificity. While the sequence alignments in this application and U. S. patent 5,972,664 are interesting and suggest the desaturase functionality of a newly characterized protein, they do not represent a structure/function relationship. Clearly, the 5-desaturase and the 6-desaturase have significant sequence homology, yet they have different chemical function. See Appendix A filed 8/28/07. The claims are directed to any deletion mutants of SEQ ID NO: 2, which has 6-desaturase activity, but the specification does not teach the core requirement for said activity. It is important to note that each polypeptide chain carries in its amino acid sequence a code that allow the polypeptide chain to fold into its specific three-dimensional structure to produce the functional protein. Said code is unknown in the art and no one can predict the ability of a peptide sequence to fold into a functional protein. Thus, the examiner has reasonable scientific bases to challenge the adequacy of the written description. The claims remain rejected.

Claims 298, 299, 301-309, 330, 343, 356, and 369 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention for the reasons set forth in the prior Office actions mailed 11/14/05 and 7/18/06.

Applicants' argue that a written description rejection requires analysis of what one of skill in the art would have understood and why they would have recognized the inventor was not in possession of the claimed invention.

Applicants arguments filed 8/28/07 have been fully considered, but they remain unpersuasive. The claims lack any support in the specification or the originally filed claims. Clearly, applicants have never envisioned the claimed invention at the time the application was filed. Applicants keep repeating that examples 1 and 2 support the claims, yet the examiner cannot find any. Applicants argue that example 2 describe the obtaining of partial cDNA clone Ma524, and states that the full-length cDNA was isolated. They further reach out to conclude that one of ordinary skill in the art would have concluded that M524 was used to screen the library, presumably, by hybridization under some unspecified hybridization conditions. Claim 298 from which all other claims are dependent requires "hybridization conditions suitable for selectively screening a recombinant DNA library using a probe comprising the complement". Neither the examiner nor one of ordinary skill in the art would know what is suitable for selectively screen or what the applicants have in mind when they wrote the claim. There are many hybridization conditions that are used to screen cDNA or genomic libraries. Obviously applicants have one particular hybridization condition that they considered suitable for screening the library, but they fail to disclose it in the specification. Clone Ma524 is described as partial cDNA in example 1, which makes it something other than SEQ ID NO:1 or complement thereof. No single statement in the specification that suggests the use of SEQ ID NO:1 or its complement as a probe to screen any libraries. Applicants failed to show where such a suggestion might be. Thus, the claims contain new matter. New matter is a *prima facie* evidence of lack of written description. Applicants must remove the new matter from the claims.

Claims 300, 310-318, 331, 344, 357, and 370 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the prior Office actions mailed 11/14/05 and 7/18/06.

In response to the above rejection, applicants argue that disclosure in the specification of a single structure capable of performing the claimed function in a 112(6) claim valid under 112 and the Office action mailed 11/1/05 indicated that a species is disclosed.

Applicants arguments filed 8/28/07 have been fully considered, but they are found unpersuasive. MPEP 2181 (II):

> 35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section **112**." *In re Donaldson Co.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

Thus, the claim is directed to a method of producing oil utilizing a transgenic plant comprising a protein or nucleic acid from *Mortierella aplina* having amino acid sequence having 60-100% sequence homology to SEQ ID NO: 1. Such a genus of 6-desaturases are not properly described in the specification and subjected to lack of written description rejection for reasons of record.

Claims 225-234, 265-274, 319-322, 326,329, 332-335, 339, 342, 345-348, 352, 355, 358-361, 365, 368, 371, and 372 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement for the reasons set forth in the prior Office actions mailed on mailed 11/14/05 and 7/18/06.

Applicants have reiterated their previous argument without any supporting evidence and amend the claims to expand their scope.

Applicants arguments filed 8/28/07 have been fully considered, but they remain unpersuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert:

> "The disclosure fully teaches the protein and DNA sequences of the *M. alpina* delta-6-desaturase, as well as methods of manipulating sequences, and testing protein function. One of skill in the art could make sequences having 60%, 80%, 90%, or 95% homology to the disclosed sequence by following the teachings in the application. ..... Applicants have further provided evidence of record that one skill can functionally screen a large number of mutants in a given amount of time".

Applicants make no effort to explain <u>why</u> they consider the disclosure of the amino acid sequence of SEQ ID NO: 1, well know methods of cloning, and assaying for delta-6-

desaturase to be enabling with respect to any variant having sequence homology of 60%, 80%, and 90%. Having the ability to look for the something does not give one of ordinary skill in the art expectation of finding it. Applicants are advised to review the previous Office action was mailed in this case keeping in mind that there is precedent in the prior art in which one of ordinary skill in the art has changed 20-40% of the amino acid residue in a protein sequence systematically and produced a desirable functional protein without undue experimentation. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 298, 299, 301-309, 330, 343, 356, and 369 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

(a) The clause "that hybridizes preferentially to the complement of the sequence depicted in SEQ ID NO: 1 under hybridization conditions suitable for selectively screening a recombinant DNA library" in claim 298 renders the claims indefinite and confusing. The conditions are not identified by the specification, and one of ordinary skill in the art would not know what the applicant have used. This rejection is made against canceled claims 275 and 279 in the previous Office action. For examination purposes only, the phrase is taken to mean any hybridization conditions.

Applicants point out that they have responded to the above rejection in the response filed 5/15/06 and suggested that the examiner revisits the response as both the lack of written description and the second paragraph issues are addressed together. They further repeated the same argument found in their responses of 11/15/06.

Applicants' arguments filed on 5/15/06, 11/1/05, and filed 8/28/07 have been fully considered, but they remain unpersuasive. The gist of applicants' response is that relative language is appropriate to define the metes and bound. The examiner is not aware and cannot identify a standard hybridization conditions that are suitable for selectively screening any cDNA library, and the specification does not teach any. The suitable conditions are identified experimentally for each nucleic acid and library, and applicants should have disclosed what are those suitable conditions are in their specification. The specification does not identify any conditions that fit the description in the claim or the standard, which would allow one of ordinary skill in the art to determine

the metes and bound of the claimed invention. Applicants merely use undefined standard to define indefinite term. The result is an indefinite claim. Claims 299, 301-309, 330, 343, 356, and 369 are included with these rejections because they are dependent on a rejected claims and do not cure its deficiencies.

Claims 323, 324, 336, 337, 349, 350, 362, 363, and 373 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 215-224, 255-264, 325, 328, 338, 341, 351, 354, 364, and 367 are allowed.

This is a RCE of applicant's earlier Application No. 09/367,013. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nashed/
Nashaat T. Nashed, Ph. D. .
Primary Examiner
Art Unit 1656